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1103326-0203

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Lundberg et al.

Serial No.

: 10/693,317

Filed

: October 23, 2003

For

: NEW PHARMACEUTICAL FORMULATION AND

**PROCESS** 

Examiner

: Sheikh, Humera N.

Group Art Unit

: 1615

### CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. 1.8

I hereby certify that this paper is being facsimiletransmitted to the U.S. Patent and Trademark Office on December 7, 2004

at the facsimile number 703-872-9306.

John M. Genova

32,224

Agent Name

PTO Reg. No.

Signature

Date of Signature

Mail Stop

ATTENTION: Examiner Humera N. Sheikh

Commissioner for Patents P.O. Box 1450 DATE: December 7, 2004 NUMBER OF PAGES: 17

Alexandria, VA 22313-1450

FAX NUMBER: 703-872-9306

# INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. §1.97(b))

Sir:

Applicants submit this communication in compliance with 37 C.F.R. §§1.56, 1.97 and 1.98.

The referenced application is the great-grandchild of U.S. Patent Application Serial No. 08/612,951, filed March 8, 1996, now US 6,013,281 (the "281 patent"), issued January 11, 2000, which is a §371 of PCT/SE96/00161, filed February 9, 1996, which claims priority to SE 9500478, filed February 9, 1995.

The assignee of the referenced application and the '281 patent is the same, i.e., Astra Akticholag.

The '281 patent was the subject of a patent infringement litigation, i.e., <u>In re Omeprazole</u>

Patent Litigation, 2004 WL 1171254 (S.D.N.Y.). Attached to this communication is Form

PTO/SB/08A identifying the court's written decision. A copy of the court's written decision is enclosed.

The '281 patent has 21 claims. However, only claims 1-3, 7, 16, 20 and 21 of the '281 patent were asserted and at issue in the litigation. The court held that the asserted claims 1-3, 7, 16, 20 and 21 of the '281 patent are invalid under 35 U.S.C. §102 in view of Korean Laid Open Patent Application No. 92-17571, filed September 26, 1992 (the "Korean patent application"). Claim 9 was also held to be invalid under 35 U.S.C. §103 in view of the Korean patent application. The court held that the Korean patent application was "laid open" and, therefore, in the public domain as of April 20, 1993, i.e., more than one (1) year before the February 9, 1995 priority date of the '281 patent.

Applicants made the Korean patent application of record in the referenced application by the Information Disclosure Statement that was filed concurrently with the referenced application on October 23, 2003.

Pages 7-12 of the enclosed written decision provide the court's discussion regarding anticipation and obviousness. Pages 12-13 of the written decision are concerned with the accused infringer's allegations of fraud and inequitable conduct in the procurement of the '281 patent. However, as set forth in the first full paragraph on page 12, top left-hand column, of the written opinion, the court stated that the defenses of fraud and inequitable conduct were mooted by the court's rulings of invalidity with respect to the asserted claims of the '281 patent.

An appeal of the court's decision, including a cross-appeal, regarding the holding of invalidity of claims 1-3, 7, 16, 20 and 21 of the '281 patent, docketed as Astra Aktiebolag v. Andrx Pharma., Nos. 04-1562, -1563, -1589, is presently pending before the Court of Appeals for the Federal Circuit.

### TIME OF TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(b)(4) before the mailing of a first Office Action on the merits after the filing of an application under §1.114, and therefore no fee should be due. However, if there be a fee due in connection with this communication, the Commissioner is authorized to charge any such fee to Deposit Account No. 23-1703.

Dated: 7 December 2004

Respectfully submitted,

John M. Genova Reg. No. 32,224

Attorney for Applicants

Customer No. 007470 White & Case LLP

Attorney's Direct Dial: (212) 819-8832

### 1103326-0203

PTO/SB/08A (08-03)
pproved for use disough 07/31/2006. OMB 0651-0011 U.S. Patent and Tradement Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction	Act of 1995, no persons are required to respond to a collection of info	mation unless it contains a valid OMB control number		
Substitute for form 1449/PTO		Complete if Known		
Substitute to 10111 1449/P1O	Application Number	10/693,317		
INFORMATION DISCLO	Filing Date	October 23, 2003		
	Lust Marined Inventor	Per Johan Lundberg		
STATEMENT BY APPLI	CANT Art Unit	1615		
(Use as many sheets as necessary)	Examiner Name	Humera N. Sheikh		
Sheet 1 of	1 Attorney Docket Number	r 1103326-0203		

U.S. PATENT DOCUMENTS								
Examiner Initials	Cite No.1	Document Number Number-Kind Code <sup>3 (//mon)</sup>	Publication Date MM-DD-YYYY	Name of Patentoe Applicant of Cited Document	Pages, Columns, Lines, Where Refevant Passages/Figures Appear			
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	<u> </u>	In re Omeprazole Litigation (2004 WL 1171254 (S.D.N.Y.)						
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